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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **RULE 56(d) UNSWORN DECLARATION OF RAMON ROSSI LOPEZ UNDER PENALTY OF PERJURY IN RESPONSE TO DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT REGARDING PREEMPTION**

1. RAMON ROSSI LOPEZ, declares under penalty of perjury under the laws of the United States of America as follows:

2. I am an adult person over eighteen (18) years of age residing in Orange County, California.

3. I am an attorney duly licensed to practice law in the State of California. I am admitted *pro hac vice* in the above captioned matter and I am a partner of Lopez McHugh,

LLP and Co-Lead counsel for In re Bard IVC Filter Products Liability Litigation, MDL No. 2641.

4. I submit this Affidavit in accordance with Rule 56(d)(2), Federal Rules of Civil Procedure, made applicable to this proceeding by CMO 22, and in response to Defendants' *Motion for Summary Judgment Regarding Preemption* (the "Motion") and a *Statement of Facts in Support of Motion for Summary Judgment Regarding Preemption* (the "SOF").

5. In Section V of the Parties' Joint Status Report for the May 3, 2017 Case Management Conference ("Report"), submitted simultaneously to the Court with this Affidavit, Plaintiffs provide the basis and arguments related to Plaintiffs' position regarding the need for additional discovery and an altered briefing schedule.

BACKGROUND

6. On February 17, 2017, counsel for Defendants requested the Court set a briefing schedule for the Motion. Plaintiffs objected on the basis that such a dispositive motion is premature and it would be more suitable for such a motion to be brought after the close of all discovery, specifically expert discovery. Plaintiffs' basis for the request to stay motion practice until after completion of expert discovery was based on Bard's joint submission statement that there would be genuine issues of material fact that could only be established by expert interpretation and opinions.

7. In response to the Court's inquiry, Bard denied that expert opinion was necessary to support its motion.

8. The Court set a briefing schedule requiring Defendants to file the Motion and allowing for Plaintiffs to review it and, if necessary, file a "Rule 56" Affidavit for the Court's

consideration identifying any additional discovery necessary to respond to the Motion. *See* CMO 22.

9. Bard filed its Motion and SOF on March 24, 2017.

10. Bard's Motion and SOF are supported by two (2) declarations. The first declarant (Carr) submitted a declaration with 136 statements; a variation of some of these statements are contained in Bard's regulatory experts' reports served on April 14, 2017. The second declarant (Van Vleet) submitted a declaration with 88 statements; a variation of some of these statements are also contained in Bard's regulatory experts' reports.

11. Although Bard does not cite its experts' reports in its Motion or SOF, Bard's expert regulatory reports provide opinions as to the 510(k) process and utilize many of the same underlying facts Bard has proffered in its SOF.

12. The declarations submitted by Bard contain conclusory statements about interactions between Bard and the FDA. However, Plaintiffs have no discovery from the FDA and no ability to cross examine any FDA personnel who allegedly interacted with Bard employees.

SPECIFIC FACTS PLAINTIFFS SEEK TO DISCOVER

13. While Plaintiffs maintain that Bard's proffered facts do not establish the extraordinary remedy of federal preemption (particularly for a Section 510k cleared device), Plaintiffs request and are entitled to discover and test the facts proffered by Bard in order to rebut the conclusions which Bard has drawn from them. Particularly, if the Court does not agree that existing case law and FDA interpretation of its 510k process demonstrate that

preemption does not apply to Plaintiffs' claims in this case, expert disclosure, and discovery will be necessary to create genuine issues of material fact.

14. For example, using many of the same "facts" Bard's regulatory expert has opined:

> Bard was in compliance with FDA rules and regulations governing the submission of 510(k) applications for the Bard IVC Filters. The 510(k) applications submitted by Bard contained the requirements specified in 21 CFR § 807.87 and were consistent with FDA guidance document for IVC filters. Based upon my experience, these 510(k) applications met industry standards and overall were complete, quality submissions.

See Report of Defense Expert Christine L. Brauer dated April 13, 2017, p. 45.

15. Bard asserts identical conclusions through its non-expert declarants. Plaintiffs expect expert testimony will establish that the 510(k) process has been, and remains, concerned with ensuring substantial similarity of a device to a predicate device, as opposed to the more rigorous premarket approval (PMA) process the FDA utilizes to evaluate a product's safety and efficacy. *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) ("As the court noted below, [t]he 510(k) process is focused on *equivalence*, not safety.") (internal citation omitted; emphasis in original).

16. Bard argues that the advent of special controls somehow changes the regulatory process, and identifies FDA's 1999 Guidance document as a special control listed in the regulations. Notwithstanding the need for expert opinion to interpret, construe, and explain the meaning of special controls in the context of the regulations, Bard's own regulatory expert states:

> These guidance documents provide recommendations and are not mandatory per se. Nonetheless from my experience, providing the recommended information and test data identified in a guidance document is often an efficient process for a manufacturer to obtain market authorization.

See Brauer Report, p. 14.

17. Specifically, in order to address Defendants' factual allegations in the SOF and to create a genuine issue of material fact, Plaintiffs need to depose Bard's experts to examine their opinions which are based on the same or similar facts which serve as the bases for conclusory statements made by the Bard employee declarants. These conclusions must be examined in the context of the meaning of regulations and purported changes in the regulatory scheme in order to sufficiently controvert Bard's positions. Similarly, Plaintiffs' experts (who hold different opinions about the PMA and 510(k) processes) need to be allowed to offer opinions and testimony on these issues looking at the same information upon which Bard relies for its Motion. Plaintiffs anticipate that their regulatory experts will explain that the special controls applicable to certain devices do not change the overall architecture of the 510(k) process or its principal aim of ensuring equivalence as opposed to safety, and that Bard witnesses and experts may need to concede such points when confronted with applicable documents and regulatory interpretations.

18. For instance, Plaintiffs' experts have disclosed in their Rule 26 Reports:

A. "As noted by FDA reviewers, 'IVC filters are class II devices regulated with special controls requiring FDA clearance of a 510(k) premarket notification, which demonstrates that the device under review is as safe and effective as a device already on the

market.' (BPVEFILTER-01-00336554-558 at 557)." *See* Report of Plaintiffs' regulatory expert David A. Kessler, p. 30 ¶ 69 (former FDA Commissioner) (Kessler Report).

B. "According to FDA: 'a 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is at least as safe and effective as the predicate.'" (*See* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k, last accessed August 9, 2016)." *See* Kessler Report, p. 30, ¶ 67.

C. "According to Defendants' expert Dr. Donna B. Tillman, Bard had an obligation to assure that (a) "the device continues to be safe and effective and that they meet FDA's quality system requirements throughout the life of the device," (b) "[a]ssessed overall, the safety and effectiveness of the device could not be worse than the predicate device;" and (c) "[the device] needs to be as safe and effective as the predicate device." (Deposition of Dr. Donna B. Tillman, 06/12/2014, 101:20-23; 116:1-3 and 120:6-7)." *See* Kessler Report, p. 30, ¶ 68.

19. Also, Plaintiffs' expert, former FDA officer, Suzanne Parisian, includes the following disclosure in her Rule 26 expert report:

> Therefore, the 1999 Guidance fully described the intended use for IVC filters that could be cleared for marketing as Class II IVC filters. The Guidance's recommendations were not considered binding for industry but was provided to industry as FDA's current thinking on the topic. Alternative approaches for supporting clearance of 510(k)s could also be proposed and used if the manufacturer's approach satisfied the requirement of the applicable statute or regulations.

Expert Report of Suzanne Parisian, M.D., pp. 26-27, ¶ 50.

20. Plaintiffs further request the opportunity to provide additional expert testimony relating to Bard's actual 510(k) clearance process. Plaintiffs expect that this testimony will show that nothing in the manner in which Bard's products reached the market was meaningfully different than the traditional 510(k) process for which courts have routinely denied preemptive effect. Moreover, experts familiar with the regulatory process for a variety of products can explain why the FDA needed clarification and additional materials from Bard in various instances given deficiencies in Bard's initial submissions.

21. In addition to expert opinion evidence, Plaintiffs seek to depose Bard declarants Mr. Carr and Mr. Van Vleet. These witnesses' declarations and the documents attached are the sole factual support for Bard's motion. Plaintiffs anticipate that these depositions will establish that they lack sufficient foundation for a number of their statements, that various statements upon which they rely are susceptible to multiple interpretations, and that they do not know in each instance what the FDA would have done had Bard changed its submission or included additional or different information, among other things.

THE FACTS SOUGHT IN DISCOVERY EXIST

22. The facts sought in discovery exist. Plaintiffs' regulatory experts have the requisite education, training and experience to explain the issues discussed above.

23. Similarly, Mr. Carr and Mr. Van Vleet presumably are available for depositions and their depositions are expected to establish several controverted issues of fact or other evidentiary deficiencies in Bard's motion.

THE SOUGHT AFTER FACTS ARE ESSENTIAL TO OPPOSE SUMMARY JUDGMENT

24. Discovery is expected to demonstrate the following critical facts:

a. The 510(k) process used by Bard is still a 510(k) process and still not focused as intently on the device's safety and efficacy;

b. The 510(k) process used by Bard was not as rigorous as a ground-up PMA process;

c. Special controls employed by the FDA for filter cases do not change the overall dichotomy between device clearance under 510(k) and device approval under PMA;

d. Much of the "extra work" Bard did during the 510(k) process was necessitated by deficiencies in Bard's submissions and underlying data and methodology, as opposed to rigors inherent in filter approval;

e. The length of time for approval of these devices is not suggestive of any particular "super 510(k)" process more akin to PMA;

f. That Van Vleet and Carr lack foundation for many of the "facts" attributed to them in Bard's SOF and their declarations; and

g. That many of the "facts" relied upon by Bard are improper conclusions and otherwise not admissible evidence.

25. These facts would preclude summary judgment because they demonstrate not only the deficiencies in many of Bard's factual allegations but also that the 510(k) process employed by Bard to bring its filters to market is still a process under which the FDA is concerned with substantial similarity as opposed to safety and efficacy of the device. The

requirements Bard attaches to the 501k process for its filters does not demonstrate or establish that it would perform as expected, intended, and represented once these devices were cleared for marketing, nor that their devices would be free of unreasonably dangerous defects in design or manufacturing once used clinically.

IMPOSSIBILITY OF DISCOVERY FROM FDA

26. Some aspects of what Bard has submitted simply are not subject to cross-examination and, therefore, Plaintiffs are denied fair and complete due process to establish a genuine issue of material fact as to many if not most of the assertions in Defendants' SOF.

27. For example, approximately one third (1/3) of the exhibits (76 of the 215 submitted in support of the declarations) summarize meetings/calls or reference calls, meetings and/or discussions with FDA representatives. Bard drafted and characterized these hearsay conversations and what the FDA was looking for in making its requests.

28. These FDA communications are with, or include, thirty-seven (37) current or former FDA employees spanning almost 20 years and involving at least 12 (twelve) separate and distinct 510k submissions and clearances. Plaintiffs have no discovery and are most likely precluded from deposing (i.e., deprived of the ability to cross examine) these witnesses their communications with dozens of Bard employees and agents as summarized by Bard's submitted SOF. It is my understanding, and has been my experience, that 21 C.F.R § 20.1 (a-b) precludes the discovery/deposition of these FDA and former FDA employees, and that even requesting discovery/depositions of these FDA employees under 21 C.F.R. § 20.1 (c) is an exercise in futility.

29. Based upon this regulatory preclusion, it is impossible for Plaintiffs to conduct discovery and present anywhere near the most relevant and compelling facts that may rebut Bard's alleged "facts" and thereby preventing Plaintiffs from the ability to present any competent or reliable issue of material fact to virtually all of those set forth in Bard's SOF. At the same time Plaintiffs object to FDA-related communications as inadmissible hearsay and therefore Bard should not be allowed to advance document based facts in support of its motion.

30. Even if Plaintiffs could conduct discovery on these FDA employees, a fanciful notion, at best, there are approximately thirty-seven (37) witnesses. While all witness depositions may not be necessary, there are still a significant number of individuals who would have to be located, subpoenaed, etc. This would cause undue delay in a case both parties have endeavored to discovery expeditiously to move to the bellwether trial phase. This is highly prejudicial to Plaintiffs since Plaintiffs strongly suspect that FDA witnesses would testify that what Bard repeatedly characterizes as exceptional effort or newly-required work was largely necessitated by Bard submitting incomplete documentation, using questionable methodology, or failing to provide backup data.

31. A June 18, 2009 Government Accountability Office report, titled "Shortcomings in the FDA's Premarket Review, Post Market Surveillance, and Inspections of Device Manufacturing Establishments," describes the results of an investigation of the division at FDA that is responsible for medical devices, including IVC filters. This is a 21-page official GAO report which included in its findings:

> Taken together, these shortcomings in both the premarket and postmarket activities raise serious concerns about FDA's regulations of medical devices.

In essence, this conclusion from this GAO investigation would potentially require discovery, including depositions of FDA and/or GAO officials, including Dr. Donna Bea Tillman, Defendants' regulatory expert who was the Director of this FDA medical device division at the time.

UNDUE DELAY

32. There are also sixty-seven (67) Bard employees associated with the exhibits attached to the declarations submitted in support of Bard's Motion. Thirty-nine (39) of those Bard individuals have not been deposed. Plaintiffs sought the depositions of some of these individuals and Bard objected. (*e.g.*, Tim Ring). Moreover, Plaintiffs did not consider depositions of many of these individuals relevant or necessary, in light of the Fourth Circuit holding that "[A]llowing 510(k) evidence would have provoked the parties to engage in a time-consuming mini-trial on whether Bard in fact complied with its provisions. Excluding 510(k) evidence avoided these risks and was therefore proper under Rule 403." *Cisson v. C.R. Bard, Inc.*, 86 F. Supp. 3d 510, 517–18 (S.D.W. Va. Jan. 20, 2015); and, in light of the later Fourth Circuit holding, citing *Cisson*, that "given its' limited probative value and the risk of confusing the jury by, inter alia, causing a battle of the experts over the robustness of the 510(k) process' safety examinations, we held that the exclusion of the 510(k) compliance evidence was not improper. . . . This relative lack of probative value, especially given a possible battle of experts over the 501(k) process underscores the risk of confusion and wasted time that would follow the introduction of this evidence." *Huskey v. Ethicon, Inc.*,

848.F.3d 151, 160 (4th Cir. 2017). Yet, Plaintiffs are now faced with the prospect of having to identify and depose those witnesses which may have undiscovered facts relevant to Bard's preemption Motion, and likely re-depose witnesses who are now offering this new, previously undisclosed information.

33. Conducting depositions of these additional employees, or even a reasonable paring down of the sheer number of them would cause undue delay. Although Plaintiffs agree that the issue of preemption is a matter of law, they disagree that Bard has asserted facts which are undisputed in its moving papers. Whereas the individuals and the documents Bard now relies upon were not relevant before, Bard's recent motion has now caused a need for additional discovery if Plaintiffs are forced to show a genuine issue of material fact.

I declare, under penalty of perjury, that the foregoing is true and correct.

Executed this 28th day of April, 2017.

RAMON ROSSI LOPEZ

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of April, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Deborah Yanazzo

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